March 28, 2017

Tonix Pharmaceuticals Enrolls First Participant in Military-Related PTSD Phase 3 Trial of FDA Breakthrough Therapy-Designated TNX-102 SL

HONOR Study to Enroll 550 Participants in Approximately 35 U.S. Sites with One Unblinded Interim Analysis at Approximately 275 Participants

NEW YORK, March 28, 2017 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a company that is developing innovative pharmaceutical products to address public health challenges, announced today that it has enrolled the first participant in the Phase 3 HONOR study of TNX-102 SL 5.6 mg, for the treatment of posttraumatic stress disorder (PTSD).

"Enrolling the first participant in the HONOR study is an important event not only to Tonix, but potentially to millions who suffer worldwide from both civilian and military-related PTSD," said Seth Lederman, M.D., Tonix's president and chief executive officer. “The HONOR study is designed to confirm the clinical benefit of TNX-102 SL to improve PTSD symptoms across several measures as demonstrated in our Phase 2 AtEase study in military-related PTSD.”

About TNX-102 SL

TNX-102 SL is an investigational new drug and has not been approved for any indication. It is a small, rapidly-disintegrating sublingual tablet containing 2.8 mg of cyclobenzaprine HCl for bedtime use. TNX-102 SL is a proprietary, Protectic™ protective eutectic formulation of cyclobenzaprine that allows for rapid systemic exposure and increased bioavailability through transmucosal delivery. Tonix is developing TNX-102 SL 5.6 mg (2 x 2.8 mg tablets), as a potential treatment for PTSD. In the Phase 2 AtEase study, TNX-102 SL 5.6 mg, taken sublingually at bedtime for 12 weeks demonstrated activity for the treatment of military-related PTSD compared to placebo, measured by a reduction in the Clinician Administered PTSD Scale for DSM-5, or CAPS-5 score. The most frequently reported adverse events were episodes of tongue numbness, which was generally transient and self-limited and related to the oral site of administration. Systemic adverse events included somnolence, dry mouth and sedation, which is similar to the known side effects of oral cyclobenzaprine. In December 2016, TNX-102 SL was granted Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA) for the treatment of PTSD.

About the Phase 3 HONOR Study

HONOR is a Phase 3 randomized, double-blind, placebo-controlled trial evaluating the

efficacy of TNX-102 SL 5.6 mg, in participants with military-related PTSD. The two-arm, adaptive design trial is designed to enroll 550 participants across approximately 35 U.S. sites. Participants in the HONOR study will be randomized to receive either TNX-102 SL 5.6 mg (2 x 2.8 mg tablets), or placebo, to be taken sublingually at bedtime daily for 12 weeks. The primary endpoint is the mean change from baseline, after 12 weeks, in the total CAPS-5 score compared between TNX-102 SL 5.6 mg, and placebo. In an End-of-Phase 2/Pre-Phase 3 meeting with Tonix, the FDA indicated its acceptance of Tonix's proposed Phase 3 studies and the planned New Drug Application data package for the registration of TNX-102 SL for the treatment of PTSD. Tonix has received FDA concurrence with the HONOR study design, including the proposal for an unblinded interim analysis (IA).

The HONOR study will have one unblinded IA by an independent data monitoring committee when the study has results from approximately 50% efficacy-evaluable participants, or approximately 275 participants, which is projected to occur in the first half of 2018. If the IA results require continued enrollment, topline results from the 550-participants trial are expected to be available in the second half of 2018. Additional details of the HONOR study are available at www.thehonorstudy.com, or http://bit.ly/2lrMZ1H.

About Posttraumatic Stress Disorder

PTSD can develop from witnessing or experiencing a traumatic event in which there was the severe threat of, or actual occurrence of, grave physical harm or death. PTSD affects approximately 8.6 million Americans and is a chronic and severely debilitating condition in which patients re-experience the horrific traumas that resulted in the condition in the forms of intrusive memories, flashbacks, and nightmares. PTSD typically is characterized by disrupted sleep, anxiety, agitation, avoidance, emotional numbness and estrangement from family and friends, guilt or negative beliefs about self, and sometimes is associated with clinical depression and suicidal thinking. Individuals who suffer from PTSD usually have significant impairment in social functioning, occupational disability, and an overall poor quality of life. PTSD is sometimes associated with substance abuse and unpredictable violent or suicidal behaviors. It is estimated that more than 19 percent of the 1.9 million U.S. veterans who were deployed to the recent conflicts in Iraq and Afghanistan suffer from PTSD.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing innovative pharmaceutical products to address public health challenges. TNX-102 SL is in Phase 3 development and has been granted Breakthrough Therapy designation by the FDA for the treatment of PTSD. PTSD is a serious condition characterized by chronic disability, inadequate treatment options especially for military-related PTSD, and an overall high utilization of healthcare services that contributes to significant economic burdens. The Protectic™ protective eutectic and Angstro-Technology™ formulation are essential elements of the proprietary TNX-102 SL composition for which a Notice of Allowance has been issued by the U.S. Patent and Trademark Office. Other development efforts include TNX-601 (tianeptine oxalate), a clinical candidate at Pre-IND (Investigational New Drug) application stage, designed for daytime use for the treatment of PTSD, and TNX-801, a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus (HPXV). HPXV has protective vaccine activity in mice, using a model of lethal vaccinia infection.

This press release and further information about Tonix are provided at www.tonixpharma.com.

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as “anticipate,” “believe,” “forecast,” “estimate,” “expect,” and “intend,” among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, substantial competition; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Tonix does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the Securities and Exchange Commission (the “SEC”) on March 3, 2016, and future periodic reports filed with the SEC on or after the date hereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date hereof.

Contacts

Jessica Smiley
Investor Relations
investor.relations@tonixpharma.com
(212) 980-9155 x185

Edison Advisors (investors)
Tirth Patel
tpatel@edisongroup.com
(646) 653-7035

Russo Partners (media)
Rich Allan
rich.allan@russopartnersllc.com
(646) 942-5588

Source: Tonix Pharmaceuticals Holding Corp.